Curtis State Office Building
1000 SW Jackson St., Suite 540
Topeka, KS 66612-1367

Kansas
Department of Health & Environment

Phone: 785-296-0461
Fax: 785-368-6368
www.kdheks.gov

Susan Mosier, MD, Secretary

Sam Brownback, Governor

Drug Utilization Review Board
Meeting Agenda, Open Session
July 13, 2016 10:00 a.m. – 2:00 p.m.

Meeting Location
HP Enterprise Services, Building #283, Capital Room
6511 SE Forbes Ave, Topeka, KS 66619

Board Members

Lauren Morton, PharmD, BCPS
James Backes, PharmD
Tim Heston, DO
John Kollhoff, PharmD
Roger Unruh, DO
Moneeshindra Mittal, MD
Judy McDaniel Dowd, PA-C
LaTonyua Rice, PharmD, CGP

KDHE-DHCF Staff

Liane Larson, PharmD
Carol Arace, Administrative Assistant

HP Enterprise Services/HID Staff

Ariane Casey, PharmD
Karen Kluczykowski, RPh
Nancy Perry, RN

MCO Staff

Jonalan Smith, PharmD, FASCP, **Sunflower State Health Plan**
Jennifer Murff, RPh, **UnitedHealthcare Community Plan**
Lisa Todd, RPh, **Amerigroup**

I. CALL TO ORDER

A. Announcements

II. OLD BUSINESS

A. Review and Approval of April 13, 2016 Meeting Minutes

III. NEW BUSINESS

A. Revised Prior Authorization (PA) Criteria

1. **Botulinum Toxins (Xeomin® [incobotulinumtoxinA])**
   Xeomin in a botulinum toxin. Prior authorization criteria were last revised in April 2016. Since that time, Xeomin has become indicated for the treatment of upper limb spasticity in adults. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Gilotrif® (afatinib)**
   Gilotrif is a tyrosine kinase inhibitor. Prior authorization criteria were initially approved in January 2014. Since that time, the medication has been approved for an additional indication of metastatic, squamous non-small cell lung cancer (NSCLC) in patients who have progressed after platinum-based chemotherapy. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Imbruvica® (ibrutinib)**
   Imbruvica is a tyrosine kinase inhibitor. Prior authorization criteria were last revised in April 2016. Since that time, the medication has been approved for use in Small lymphocytic lymphoma (SLL). The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **LABA-Anticholinergic Combinations (Bevespi Aerosphere® [glycopyrrolate/formoterol])**
   Bevespi Aerosphere is an inhaled combination of a long-acting beta-agonist (LABA) and an anticholinergic agent indicated for the treatment of chronic obstructive pulmonary disease (COPD). Prior authorization criteria for these combination agents were initially approved in January 2016. Since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Bevespi Aerosphere.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Makena® (hydroxyprogesterone caproate)**
   Makena is a progestin indicated for the prevention of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Prior authorization criteria were initially approved in June 2011. Since that time, the medication is now available in a 1 mL vial. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Remicade (Inflectra® [infliximab])**
   Inflectra is the first biosimilar available. Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Prior authorization criteria for these combination agents were last revised in April 2016. Since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Inflectra.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **SGLT2 Inhibitor Combinations (Invokamet ® [canagliflozin/metformin], Synjardy® [empagliflozin/metformin], Xigduo XR [dapagliflozin/metformin])**
   SGLT2 inhibitor combinations are indicated for the treatment of type 2 diabetes mellitus. Prior authorization criteria for these combination agents were initially approved in April 2015. Since that time, new combination agents have been approved. The prior authorization criteria is being revised to include new agents, Invokamet, Synjardy, and Xigduo XR.
   i. Revised PA Criteria

ii. *Public Comment
iii. Board Discussion

8. **Long-Acting Opioid Dose Optimization (Xtampza ER® [oxycodone ER])**
Xtampza ER is an opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Prior authorization quantity criteria for these opiate agents were last revised in October 2015. Since that time, a new agent have been approved. The prior authorization criteria is being revised to include the new agent, Xtampza ER.
    i. Prior Authorization Criteria
    ii. *Public Comment
    iii. Board Discussion

9. **Opana ER® (oxymorphone ER)**
Opana ER is an opioid agonist indicated for the management of pain. Prior authorization quantity criteria for this opiate agent were initially approvd in October 2015. Dosing is being revised. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.
    i. Prior Authorization Criteria
    ii. *Public Comment
    iii. Board Discussion

B. New Prior Authorization (PA) Criteria

1. **Cinqair® (reslizumab))**
Cinqair is a monoclonal antibody (respiratory) indicated for the add-on maintenance treatment of severe asthma in adults with an eosinophilic phenotype. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.
    i. Prior Authorization Criteria
    ii. *Public Comment
    iii. Board Discussion

2. **Ocaliva® (obeticholic acid)**
Ocaliva is a farnesoid X receptor agonist indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.
    i. Prior Authorization Criteria
    ii. *Public Comment
    iii. Board Discussion

3. **Sernivo® (betamethasone dipropionate)**
Sernivo is a topical corticosteroid indicated for the treatment of mild to moderate plaque psoriasis in adult patients. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.
    i. Prior Authorization Criteria
    ii. *Public Comment
    iii. Board Discussion

4. **Taltz® (ixekizumab)**
Taltz is a humanized interleukin-17A antagonist indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Prior authorization criteria

is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

i. Prior Authorization Criteria
ii. *Public Comment
iii. Board Discussion

5. **Venclexta® (venetoclax)**
Venclexta is a BCL-2 inhibitor indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA approved test, who have received at least one prior therapy. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

i. Prior Authorization Criteria
ii. *Public Comment
iii. Board Discussion

6. **Zinbryta® (daclizumab)**
Zinbryta is an interleukin-2 receptor blocking antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS). Because of its safety profile, the medication should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

i. Prior Authorization Criteria
ii. *Public Comment
iii. Board Discussion

7. **Probuphine® (buprenorphine implant)**
Probuphine is a partial opioid agonist indicated for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet or generic equivalent). Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

i. Prior Authorization Criteria
ii. *Public Comment
iii. Board Discussion

8. **Epclusa® (sofosbuvir/velpatasvir)**
Epclusa is a direct-acting antiviral indicated for the treatment of hepatitis C virus (HCV) in patients with genotype 1-6. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

i. Prior Authorization Criteria
ii. *Public Comment
iii. Board Discussion

9. **Brand Metformin ER Step Therapy**
Step therapy for brand name metformin ER products is being proposed to ensure cost-effective use.

i. Prior Authorization Criteria
ii. *Public Comment
iii. Board Discussion

10. **Brand ARB-CCB Combinations Step Therapy**
Step therapy for brand name ARB-CCB combination products is being proposed to ensure cost-effective use.

i. Prior Authorization Criteria
ii. *Public Comment

iii. Board Discussion

C. Mental Health Medication Advisory Committee (MHMAC)

1. **Opioid Dependence Agents**
   At the May 2016 MHMAC meeting, the committee approved the criteria for opioid dependence agents. Prior authorization criteria are being proposed to include the exclusion of coverage by those beneficiaries concurrently prescribed benzodiazepines.
   i. MHMAC PA Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Use of Stimulant Medications in Adults Ages 18 and Older**
   At the May 2016 MHMAC meeting, the committee approved the criteria for ADHD medications for adults. Prior authorization criteria are being proposed to require an appropriate diagnosis or prescriber specialty.
   i. MHMAC PA Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Use of Stimulants and other ADHD Agents in Children Ages 3 and Younger**
   At the May 2016 MHMAC meeting, the committee approved the criteria for ADHD medications for children. Prior authorization criteria are being proposed to require an appropriate prescriber specialty for patients under the age of 3 years old.
   i. MHMAC PA Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Stimulants and Other ADHD Agents Dosing Limits**
   At the May 2016 MHMAC meeting, the committee approved the criteria for ADHD medication dosing limits. Prior authorization criteria are being proposed to limit the maximum daily dose allowed before a prior authorization is required.
   i. MHMAC PA Criteria
   ii. *Public Comment
   iii. Board Discussion

D. Miscellaneous Items

1. **Managed Care Organization Annual Reports**
   Amerigroup, United Healthcare, and Sunflower will present reports detailing utilization trends and provider education efforts for 2014.
   i. Overall MCO Utilization Data – Liane Larson, PharmD
   ii. Amerigroup Individual Report – Lisa Todd, RPh
   iii. United Healthcare Individual Report – Jennifer Murff, RPh
   iv. Sunflower Individual Report – Jonalan Smith, PharmD
   v. *Public Comment
   vi. Board Discussion

IV. APPOINTMENT OF A NEW CHAIR

V. OPEN PUBLIC COMMENT

VI. ADJOURN

Lunch will be provided for the DUR Board members.
The next DUR Board meeting is scheduled for October 13, 2016.

*Public comment is limited to five minutes per product; additional time will be allowed at the DUR Board's discretion. Informal comments will be accepted from members of the audience at various points in the agenda.

****THIS AGENDA IS SUBJECT TO CHANGE****